



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,505	02/18/2004	Rafail Zubok	532-3X6	2913
530 7590 01/24/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER CUMBERLEDGE, JERRY L				
ART UNIT		PAPER NUMBER		
3733				
MAIL DATE		DELIVERY MODE		
01/24/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,505

Applicant(s)

ZUBOK ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/05/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Pat. 6,730,127 B2) in view of Benezech et al. (US Pat. 6,235,059 B1).

Michelson discloses a drill assembly, comprising: an intervertebral disc replacement device (Fig. 1, ref. 102) including first (Fig. 2, ref. 106) and second members (Fig. 2, ref. 108) for insertion into an intervertebral disc space of a spinal column (Fig. 10), the first member including a first flange (Fig. 4, near ref. 136) having at least one first through hole (e.g. Fig. 3, ref. 116) and the second member including a second flange (Fig. 4, near ref. 138) having at least one second through hole (e.g. Fig. 3, ref. 116); an insertion plate (Fig. 2, ref. 122) for maintaining the first and second members in registration with one another (Fig. 2), the insertion plate including a first alignment element (Fig. 1, ref. 136); and a drill guide removably connected with at least the insertion plate (Fig. 22, ref. 282), the drill guide including: a shaft (Fig. 22) having a proximal end and a distal end (Fig. 22); and a guide member (Fig. 22, end portion near ref. 294) disposed at the distal end of the shaft and operable to engage the insertion plate (Fig. 22), wherein the guide member includes at least one guide bore (Fig. 22, ref.

294a) aligned with one of the first or second through holes (Fig. 22) and an area of a vertebral bone of the intervertebral disc space to which one of the first and second members of the intervertebral disc replacement device is to be attached (Fig. 22) and a second alignment element (Fig. 22, prong of guide member) engaged with the first alignment element of the insertion plate. The first alignment element and the second alignment element enable a target orientation of a longitudinal axis of the guide bore relative to at least one of the vertebral bone and one of the first and second members of the intervertebral disc replacement device (Fig. 22). One of the first alignment element and the second alignment element includes an alignment stem (Fig. 22, prong of guide member) and the other of the first alignment element and the second alignment element includes an alignment bore (Fig. 1, ref. 136), the alignment stem being receivable within the alignment bore to enable the target orientation of the longitudinal axis of the guide bore (Fig. 22). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, surface of ref. 106) and the first through hole is capable of receiving a bone screw for fastening the first member to the vertebral bone of the spinal column (Fig. 2); and the guide member of the drill guide further includes a third alignment element (Fig. 22, second prong of guide member) operable to engage the first through hole of the first flange when the alignment stem is received within the alignment bore to further enable the target orientation of the longitudinal axis of the guide bore. The guide member includes a posteriorly directed surface and a spaced apart anterior directed surface (Fig. 22). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 22). The first member of the

intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, surface of ref. 106) and at least two first through holes (e.g. Fig. 3, ref. 116) for receiving respective bone screws for fastening the first member to the vertebral bone of the spinal column; and the guide member of the drill guide further includes at least third (Fig. 22, second prong of guide member) and fourth alignment elements (Fig. 22, second ref. 294a) extending transversely from the posteriorly directed surface of the guide member and each being operable to engage a respective one of the first through holes of the first flange when the alignment stem is received within the alignment bore to further enable the target orientation of the longitudinal axis of the guide bore. The guide member includes at least two guide bores (Fig. 22, ref. 294a), each being disposed at least partially through respective ones of the third and fourth alignment elements such that respective target orientations of longitudinal axes of the guide bores are directed through respective ones of the first through holes.

Michelson discloses a drill assembly comprising: an intervertebral disc replacement device (Fig. 1, ref. 102) including first (Fig. 2, ref. 106) and second members (Fig. 2, ref. 108) for insertion into an intervertebral disc space of a spinal column (Fig. 10), the first member including a first flange (Fig. 4, near ref. 136) having at least one first through hole (e.g. Fig. 3, ref. 116) and the second member including a second flange (Fig. 4, near ref. 138) having at least one second through hole (e.g. Fig. 3, ref. 116); an insertion plate (Fig. 2, ref. 122) for maintaining the first and second members in registration with one another, the insertion plate including a first alignment element (Fig. 1, ref. 136); and a drill guide (Fig. 22, ref. 282) removably connected with

at least the insertion plate, the drill guide including: a shaft (Fig. 22) having a proximal end and a distal end (Fig. 22); and a guide member (Fig. 22, ref. 294a) disposed at the distal end of the shaft (Fig. 22) and including at least one guide bore (Fig. 22, ref. 294a), a second alignment element of the guide member (Fig. 22, prong of guide member) engaged with the first alignment element of the insertion plate (Fig. 22), wherein the guide member is operable to achieve at least first and second alignment modes with respect to the insertion plate (Fig. 22) in the first alignment mode, the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with the first through hole of the first member and an area of a first vertebral bone of the intervertebral disc space to which the first members of the intervertebral disc replacement device is to be attached, and in the second alignment mode (Fig. 22), the guide member is operable to engage the insertion plate such that the at least one guide bore aligns with the second through hole of the second member and an area of a second vertebral bone of the intervertebral disc space to which the second members of the intervertebral disc replacement device is to be attached (Fig. 22). One of the first alignment element and the second alignment element includes an alignment stem (Fig. 22, prong of guide member) and the other of the first alignment element and the second alignment element includes an alignment bore (Fig. 1, ref. 136), the alignment stem being receivable within the alignment bore to enable rotational adjustment of the guide member relative to the insertion plate and to achieve the first and second alignment modes (Fig. 22). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, surface of ref. 106) and the first through hole is

capable of receiving a bone screw for fastening the first member to the first vertebral bone of the spinal column (Fig. 2); the second member of the intervertebral disc replacement device includes a second vertebral contact surface (Fig. 2, surface of ref. 108) and the second through hole is capable of receiving a bone screw for fastening the second member to the second vertebral bone of the spinal column (Fig. 2); and the guide member of the drill guide further includes at least a third alignment element (Fig. 22, second prong of guide member) operable to: (i) engage the first through hole of the first flange when the alignment stem is received within the alignment bore in the first alignment mode to further enable a first target orientation of the longitudinal axis of the guide bore, and (ii) engage the through hole of the second flange when the alignment stem is received within the alignment bore in the second alignment mode to further enable a second target orientation of the longitudinal axis of the guide bore. The guide member includes a posteriorly directed surface and a spaced apart anteriorly directed surface (Fig. 22). The alignment bore has a longitudinal axis that is offset from a longitudinal axis of the shaft (Fig. 22). The first member of the intervertebral disc replacement device includes a first vertebral contact surface (Fig. 2, surface of ref. 106) and at least two first through holes (e.g. Fig. 3, ref. 116) for receiving respective bone screws for fastening the first member to the first vertebral bone of the spinal column; the second member of the intervertebral disc replacement device includes a second vertebral contact surface (Fig. 2, surface of ref. 108) and at least two second through holes (e.g. Fig. 3, ref. 116) for receiving respective bone screws for fastening the second member to the second vertebral bone of the spinal column; and the guide

member of the drill guide further includes at least a third (Fig. 22, second prong of guide member) and fourth alignment elements (Fig. 22, second ref. 294a) each operable to: (i) engage a respective one of the first through holes of the first flange when the alignment stem is received within the alignment bore in the first alignment mode, and (ii) engage a respective one of the second through holes of the second flange when the alignment stem is received within the alignment bore in the second alignment mode (Fig 22). The guide member includes at least two guide bores (Fig. 22, ref. 294a).

Michelson discloses the claimed invention except for the insertion plate being removably connected with the first and second members.

Benezech et al. discloses an intervertebral disc replacement device (Fig. 1) that comprises an insertion plate (Fig. 1, ref. 12) that can either be removably connected with first and second members or integrally formed with first and second members (Fig. 1) (Fig. 3)(column 2, lines 35-47).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the insertion plate of Michelson, which is integrally formed with first and second members, as being removably connected with the first and second members, since Benezech teaches that the plate can either be removably attached or integrally formed with first and second members (Fig. 1) (Fig. 3)(column 2, lines 35-47).

Michelson in view of Benezech disclose the claimed invention except for the second alignment element of the guide member includes the alignment bore extending from the posteriorly directed surface at least partially through the guide

member toward the anteriorly directed surface; and the second alignment element of the insertion plate includes the alignment stem extending in an anterior direction for engagement with the alignment bore. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have reversed the positions of the alignment bore and the stem of Michelson in view of Benezech, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Michelson in view of Benezech disclose the claimed invention except for each guide bore being disposed at least partially through respective ones of the third and fourth alignment elements such that in the first alignment mode, first and second longitudinal axes of the guide bores are directed through respective ones of the first through holes of the first flange of the first member of the intervertebral disc replacement device, and in the second alignment mode, first and second longitudinal axes of the guide bores are directed through respective ones of the second through holes of the second flange of the second member of the intervertebral disc replacement device; the guide bore is disposed at least partially through the third alignment element such that the target orientations of the longitudinal axis of the guide bore may be directed through the respective first or second through holes in the first and second alignment modes; the guide bore is disposed at least partially through the third alignment element such that the target orientation of the longitudinal axis of the guide bore is directed through the first through hole. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the guide.

bores being disposed at least partially through respective ones of the third and fourth alignment elements such that in the first alignment mode, first and second longitudinal axes of the guide bores are directed through respective ones of the first through holes of the first flange of the first member of the intervertebral disc replacement device, and in the second alignment mode, first and second longitudinal axes of the guide bores are directed through respective ones of the second through holes of the second flange of the second member of the intervertebral disc replacement device; the guide bore being disposed at least partially through the third alignment element such that the target orientations of the longitudinal axis of the guide bore may be directed through the respective first or second through holes in the first and second alignment modes; the guide bore is disposed at least partially through the third alignment element such that the target orientation of the longitudinal axis of the guide bore is directed through the first through hole, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Response to Arguments

Applicant's arguments with respect to claims 1-10 and 12-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)

Application/Control Number:
10/781,505
Art Unit: 3733

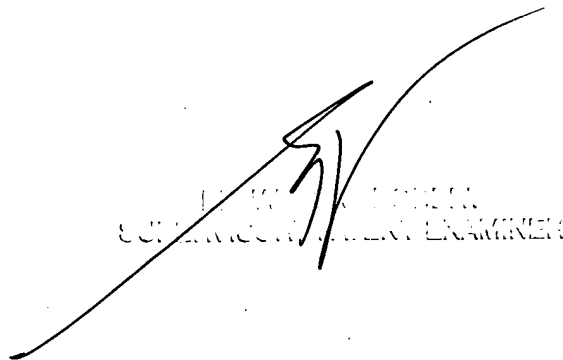
Page 10

272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EXAMINER